NAFTA COORDINATION MEETING – 9 January 2001.

Participants:
Robert Wurz – Development Project Leader
Dick Fuelner – Regulatory Affairs
Dirk Drost – Development Project Planning Head
Karen Stumpf – Regulatory Support Leader
Janis McFarland – Regulatory Affairs Head
Jennifer Shaw – Env. Stewardship & Regulatory Policy Leader
John Purdy – Environmental Fate Manager, Canada
Tom Beidler – Regulatory Policy Manager
Judy Shaw – Government & Public Affairs Director, Canada
Donna Houghton – Toxicology Manager, Canada
Duane Fairbairn – Regulatory Team Leader, Canada
Marian Stypa – Head Biology Development & Regulatory for Canada
Greg Watson – Regulatory Team Leader, Herbicides

ACTIONS

1. Provide feedback to Karen regarding information needs and RA intranet site – ALL – by 03/30. Ongoing.
2. Provide regulatory outlook for Mexico and communicate to group – Caydee to follow-up with Maurillio in Mexico by 01/30. JLS to circulate MX registration lists to entire team.
3. All to provide electronic copies of presentations presented in meeting to Jennifer – by 01/12. Notes covered highlights..
4. Committee involvement list to be compiled – JCS, JLS, Tom Beidler – by 02/28. Completion ongoing. Overview of document at next meeting.
5. Action for Judy and Jennifer Shaw to compile product issue management with industry influencing. – by 02/28 This meeting agenda.
6. Janis to report back on functioning of global PLTs and LtS teams and how these are to interface with NAFTA. – by 01/19. Item 9 this meeting agenda.
7. Send out notes from meeting – JLS – by 01/12 Done
8. Set-up next NAFTA Coordination meeting for Tues May 01 – JLS, RW (Note: In organizing meetings allow timing for PDT activities around NAFTA coordination meetings) Done
9. Decide what we want to call this group at the next meeting – ALL. Suggestions at Lunch.
10. Work-up analysis of "improve" list and issues to input into the next meeting. Determine what this group can realistically address – JLS, RW by 02/28.
11. Agree scope and mandate of team at next meeting – ALL by 5/01. Postpone to fall for MX involvement.
12. Marian and Judy to provide NNRT mission to JLS and RW, consider alternating chairs from different countries. By 01/30 . Done.
13. Judy to send import tolerance lists to JLS to circulate with minutes – ASAP. Agenda item this meeting.

14. Provide list of PDTs that Canada, MX want representation on – MS to circulate to group by 01/30. Done for CN and MX.
15. Determine the HAES representative on NAFTA Coordination Team – DD, JLS to raise with Gary Dickson (need a core member and ad hoc members) – by 01/19. Done – Gary Dickson.
16. Dirk to follow-up on and feedback to group (by 2/12)
    - study and protocol review process to include input from regulatory product managers
    - project approval (change) process

AGENDA

- Introduction – team emphasis – what we are trying to achieve is to function as a region without the added bureaucracy. (Janis)
- Scope of the team (Jennifer)
  - Primary overall coordination on NAFTA processes for registration activities.
  - Regional management of product registrations
  - Issue management
  - Regular Team Members
- Regulatory Outlook in NAFTA and Country specific circumstances
  - Janis – EPA/US
  - Marian – PMRA/CAN
  - Maurilio – CICOPLAFEST/MEX
- Project Coordination in Syngenta – Dirk
  - Project approval in NAFTA & Global
- Brainstorm the historical key products/projects then the future products/projects that have required close regional cooperation. Identify successes and areas of improvement. (Robert)
- Specific Process areas (How do we arrive at a NAFTA position/view) (Robert to facilitate)
  - Influencing the Industry & Regulatory Bodies – What are the key areas of focus for Syngenta? (Jennifer)
  - Decision process for new studies (Caydee)
  - Coordination for new ai development – PDT. Representation on Global PLT. Will CAN or MX develop an a.i. US is not interested in? (Marian)
  - Product issue management (Judy)
  - NAFTA information management (Karen)
- Draft the Guidelines for processes (Assign responsibilities)
- Wrap-up (Jennifer)
  - Frequency of Meetings
  - Reaffirm Scope
  - Action plans

Introduction – Janis McFarland

Key Success Factors:

- Process – simple, transparent, flexible
- Treat regulators as very important customers & gain respect
- Short registration timelines & coordinated regulatory functions
- Regulatory Coordination & synergies for products
- NAFTA process – gain appreciation of issues, interworking among country regulatory bodies
- Group to focus on 1. Product Development 2. Regulatory Programs and 3. Issue Management

Discussion Topics:

- Tools for tracking & Planning
- Product Dev Team formation
- Coordination with HAES & Global Regulatory Affairs
  Joint Reviews
- Border Pricing
- Communication with global, corporate etc

Policy Issues with Potential to Impact Business:

- HCB
- Endocrine Disruption
- Q*
- Human Testing
- Water Methodology Development
- Cumulative Methodology
- Inert Regulation – current issue in Canada
- Formulation Changes
- Study Design Differences (e.g., field dissipation studies)
- Ecozone categories
- Efficacy differences among countries within NAFTA
- UFs
- Differences in Risk Assessment Methods and Policy for decision making

Canada Regulatory Perspective - Marian Stypa

- Good science & effective rapport to give short timelines to registrations.
- Utilization of grower groups (EPA suggested we bring this element in earlier)
- Identify Political Hook to implement plan
- Learn from experiences with Joint Reviews (Focal point for PMRA, needs to be carefully managed by Syngenta). Differences of opinion within group regarding Joint Reviews
- Need to include the science function in deliberations. Need effective communication across functions.
- Need to look for competitive advantage and be leaders opposite policy. Must do more than issue management. Must also look for opportunities.

- Need to have science function representation at a senior level on NAFTA Coordination Core Team
- The Core group needs to make conscious decisions
- Need to develop interface between this group and global
- Janis's team to carry the burden of regional representation. There will be some exceptions.

BIG ISSUES agreed by Group

- Joint Review CN/US
- Global Reg/Harmonize/Sharing
- PDT Teams – NAFTA/GLOBAL
- NAFTA/Global Issues/PR management
- Process for Final Reports, Protocols & Tier Summaries

USEPA Regulatory Outlook

Politics:

- New Administration that is pro business
- No changes to FQPA
- More litigation by public interest groups (to Agency, Syngenta (e.g., zines))
- No big changes for 6-9 months
- More favorable decisions unlikely for some time (very beaurocratic)

People:

- New AA may have more business/user orientation
- New AA will make changes within OPP
- New people may manage key science & reg programs
- Poor morale within Program likely to get worse (high work load)

Program Issues:

- How to finish reregistration
- Major resource issues
- Priorities will remain the same
  1. Finish OPs, carbamates, B2s and atrazine (not 2001
  2. New chemicals reduced risk
  3. Refine modeling , water methods etc
  4. Cumulative risk decisions
  5. Funding stability for program

- Reevaluate current policies
- Human study, 99.9, cholinesterase, water , defaults assumptions in modeling

Predictions:

- Much slower & more confusing regulatory picture for a while
- Turmoil within program as people and policies are changed
- Fewer new ai decisions

Opportunities:

- Offer new constructive ideas, access to expertise, commitment to work cooperatively
- Demand clear understanding of process and opportunity to participate
- Build relationship with user community
- Demonstrate leadership within business
- Assure OPP of Syngenta commitment to work with them and commitment to science
- Work with EPA management to develop a more transparent process

PMRA/CANADA

Key principles:

- Each country responsible for own authority, & business result
- Coordination of business plans
- NAFTA HQ satisfies NAFTA country customer needs
- Increased PMRA/CICOPLAFEST/EPA contact across organization levels therefore harmonization needs to be managed.

Organization for Regulatory & Biological Development:
Field Development managers; Registrations Head; Chem Services & SHE Mgr, Gov't Affairs Mgr, Data Analyst, 3 Tech Reg Mgrs (tox, residues, e-fate)

PMRA:

- No change of government. PMRA Head reports to Minister of Health, Minister changes as government changes.
- Wendy Sexton new role as Chief Registrar (team of 20 reporting to her)
- Good relationship with key individuals in PMRA
- List of 8 products for reregistration (dicamba & diazinon), focus on home use
- Mandate to look for alternatives (biocontrol)
- Large turnover rate in PMRA (30% TO rate) – loose history with individuals, very little expertise especially residue area, lack of understanding of agriculture, puts considerable demands on ability to effectively dialogue
- Being closely watched by competitors therefore Syngenta is a target

PDT's in Canada:

- Four Product Development teams focused on region in Canada
- Coordinating Body at Higher Level
- Canada will have representation (Registration Manager with scientist as required) on NAFTA PDTs for key Canada products

Registration plan developed for Syngenta. All information will be in NEXUS for NAFTA to generate the information that business wants.

MEXICO

- Need to get Regulatory Output for Mexico from Maurilio.
- Syngenta needs to expect major changes in Mexico and be prepared to manage this.
- Political process at higher levels
- Changes expected in Head of Health and Safety
- No new submissions accepted since June 1999
- Important business, expected to be the fastest growing business in NAFTA
- EPA has held training sessions with Mexican reviewers (FQPA etc)
- Loss of internal regulatory expertise in Mexico
- US and Canada need to put in considerable effort to build bridges and support Mexico

PROJECT COORDINATION – Dirk Drost

- Objectives for NAFTA Product Development are overall portfolio and project mgmt, drive selection & development of projects, provide process for review, manage product lifecycle, gain technical & commercial ownership of projects
- Five experienced Project Leaders, One Portfolio Analyst, Admin
- Systems – NEXUS2 as the Project Planning, Project Management & Portfolio Tool
- Various steps in process with decision makers identified at each step
- Objective to get a visible, transparent workslate for NAFTA
- Details of annual selection process on intranet site for development planning
- Ideas start in January 2001 for 2002.
- Project leaders lead the PD process also proposed that they lead the PDTs, focus on timeline, deliveries to specifications, managing problems as they arise
- Portfolio analyst will track whether timelines are being met by process, ensure correct emphasis for resource allocation & planning that takes into account new issues, regulations, other changes, cost and time implications from emerging issues.
- There will be a prioritization within NAFTA for NAFTA projects.
- Vern Hawkins PPM will be accountable for ensuring adequate resource for NAFTA development projects supported by Janis McFarland, Dirk Drost, Mike Moss.
- Maintaining service from HAES that is centrally resourced will be an issue.

PDT's for NAFTA (product or crop focused):

- Representation – Project Leader, Brand Lead, Technical Brand Lead, Regulatory Affairs, Tox & Human Safety Assessment, Technology & Projects (Formulations), Environmental Safety,
- ad hoc representation – Canada, Mexico, Bus Analyst, strategic crop marketing and/or crop manager.

Link to Global needs to be developed ?

NAFTA will manage NAFTA projects and report on status.

Dirk presented the concept of a Development Steering Committee for NAFTA to meet our NAFTA strategic goal – steering committee would take accountability. This may be justified given the size of the resource expenditure in NAFTA.

Brainstorm

1. SUCCESSES
   - Open transparent dialogue with regulators
   - Issues raised with NNRT allowed better understanding and respect
   - Diazinon meetings were successful
   - Coordination of protocols in Res and Env. Good protocol reviews by regulators prior to initating the study
   - Integration effort showed good coordination across NAFTA
   - Pioneered joint review process
   - Novartis NAFTA involvement in TWG
   - Reduced Risk Rationales
   - Issues Management

2. AREAS TO IMPROVE
   - Formulation area – need to recognize difference between 2 countries. Changes to formulations are a major expense in Canada
   - Improve dialogue on toxicology between 2 countries. Where agency has raised a concern this needs to be addressed. Communication among agencies.
   - Inerts & PC – improve communication as Canadian issue heats up
   - Tier 2 & 3 summaries required in Canada. Look for opportunity to adopt these. Need to be proactive on electronic submissions.
   - How can we improve on capitalizing on the benefits to fit within a grower strategy. Need to be able to package and communicate benefits.
   - Import tolerance planning
   - Need to pay closer attention to merging issues
   - Need to do Reduced Risk Rationales more efficiently, need to match categories
   - Need to refine differences in Risk Assessment between PMRA/EPA
   - Regulatory Policy issues driving additional studies. Make sure regulatory needs for new science are communicated (uncertainty factors, Q*), this may include studies conducted for communication purposes. Tracking of proactive activities – HAES issue

Specific Process areas

Influencing the Industry & Regulatory Bodies – What are the key areas of focus for Syngenta? (Jennifer)
   - Categories of Bodies to Consider: Task Forces, Trade Associations, Grower, Global , Government sponsored

- Identify different types and levels of activity required for each committee in order to capitalize on Syngenta time spent on committees
- Compile list and activities for influencing. Identify level and type of activity required. Consider impact on resource expenditure, ability to sell, ability to Register. Identify whether short, medium and long-term effort.
- NAFTA Coordination team to sort by country & review from the perspective of each country
- Use this as an opportunity to coordinate influencing across the region

NAFTA information management (Karen)
Regulatory Support Group will provide internal and external Syngenta customers with regulatory assistance and expertise to:

- Achieve regulatory objectives within timelines
- Maintain credibility with regulatory agencies through timely compliance
- Maintain & enhance relationships with external customers
- Meet all product labeling needs
- Comply with EPA labeling initiatives

The group will develop and establish archival and tracking systems for regulatory information within NAFTA
The types of information to be maintained need to be agreed.

- Copies of submissions to be made available to countries and reviews (hard copies & pdf). Need to understand exactly what has already been submitted in US.
- Canada and MX & US need to review what they need within SAM.

Science review prior to submission needs to occur within PDT
Process needed for final reports, Protocol Review and Tiered summaries. Define protocols that NAFTA regulatory need to review.
RA intranet website to reflect the needs of NAFTA

Decision process for new studies (Dirk)

- Changes can be authorized by Project Leader where still within cost, time
- Chairman of PDT needs to make decisions on bigger changes
- Where NAFTA Product Development Portfolio is impacted, this needs to be flagged to PPM heads
- Need to use flexibility to free up money within NAFTA for new studies within NAFTA where necessary. First objective to find resource within funds allocated for NAFTA development.
- Financial and emotional hurdles to manage. Rationales can be provided for each or both.
- Decision-making via strong planners, PDT, PPM Heads for NAFTA.

Coordination for new ai development – PDT. Representation on Global PLT. (Marian)

- Janis will provide feedback from global meeting on operations of PLT and LtS teams and link to NAFTA

Product issue management (Judy)

- Environmental issues (water, air, sediment, endocrine)
- Business issues (formulant (inert), business confidentially, IPM definition, of label reduced rates, etc)
- 8 products for urban use that PMRA want to ban
- atrazine
- propaconazole – ED, microcontaminant
- HCB – chloro (also other microcontam), atrazine
- Chlordenafop
- Diazinon
- Revaluation of older products – resource intensive, needs to be analysed, need portfolio to be rationalized
- Used NNRT to raise awareness of issues and to manage issues
- Link to influencing within industry.